AF

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Re App	:	Stephen Nuss		
Serial No.	:	09/760,136	:	Confirmation No. 2264
Filed	:	January 12, 2001	:	
For	:	TITANIUM MOLYBDENUM ALLOY GUIDEWIRE		

LETTER

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

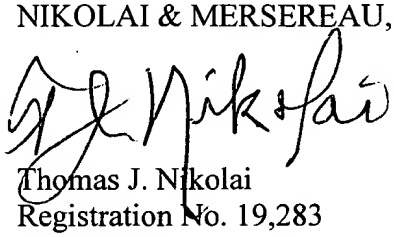
Dear Sir:

Responsive to the Official Communication of November 6, 2006, enclosed is a further Revised Appeal Brief for Appellant which includes a revised Section V that identifies claims 12 and 20 as the independent claims and which maps the wording of those claims onto Appellant's drawing and specification. If the "Order Returning Undocketed Appeal to Examiner" mailed June 7, 2006, and the Examiner's Notification of Non-Compliant Appeal Brief mailed October 16, 2006, had indicated the need to revise Appellant's Brief in the manner indicated in the Notification of Non-Compliant Appeal Brief mailed November 6, 2006, the asserted deficiency would have been addressed earlier.

Hopefully, the Examiner and the Patent Appeals Specialist will now find Appellant's Brief to be in full compliance with 37 C.F.R. 37.

Respectfully submitted,

NIKOLAI & MERSEREAU, P.A.



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SECOND REVISED APPEAL BRIEF FOR THE APPELLANT

Mail Stop Appeal Brief – Patents
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Alexandria, VA 22313-1450

I. REAL PARTY IN INTEREST

The real party in interest is Minnesota Medical Development, Inc., whose address is 14305 - 21st Avenue North, Suite 100, Plymouth, MN 55447, by virtue of an Assignment from the inventor, recorded January 14, 2002 at Reel 012589 Frame 0729.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the owner of the subject application, the owner's legal representative, or the inventor which will directly affect or be directly affected by or have bearing on the Board of Patent Appeals and Interferences in the pending appeal to the present knowledge of the undersigned.

III. STATUS OF THE CLAIMS

The present application was filed on January 12, 2001 containing claims 1-11. On February 13, 2002, a first Office Action was mailed, rejecting claims 9-11 under 35 U.S.C. §112 and claims 1-4, 6 and 9-11 were rejected on 35 U.S.C. §102(b) citing the Fagan et al patent 6,720,300. Claim 5 was rejected under 35 U.S.C. §103 on the combination of Fagan et al in view of Sepetka 5,551,443.

On May 10, 2002, appellant filed an amendment canceling the original 11 claims and adding new claims 12-37. This amendment was dated as received by the USPTO on May 31, 2002. While the specification correctly spelled out the constituents of the Beta III titanium alloy as comprising 75-83% titanium, 8-14% molybdenum, 4-8% zirconium and 2-6% tin, by weight. Other places in the specification and the newly added claims erroneously called for zinc rather than zirconium.

On October 3, 2002, the USPTO mailed a Notice of Allowability of claims 12-37. To correct the specification and claims, applicant filed an amendment on October 16, 2002 changing "zinc" to "zirconium" throughout.

At this point, the Examiner imposed a requirement for restriction between claims 12-27 drawn to the guidewire itself and claims 28-37 drawn to the method of making the guidewire. Applicant thereupon filed an election of claims 12-27 with traverse on January 30, 2003.

On April 22, 2003, the Examiner allowed claims 12-27 and held that claims 28-37 were subject to restriction/election. Applicant then filed an Amendment Under Rule 312 on May 13, 2003 amending claims 28 and 33 to make those method claims generic and canceling claims 29, 34 and 36.

In an Advisory Action mailed July 1, 2003, claims 12-27 were again indicated as allowed, but the amendments to claims 28-37 were not entered because new issues were alleged to have been raised. A divisional application was then filed by appellant containing method claims 28-37 and those claims were cancelled from the subject application.

Rather than receiving the expected Notice of Allowance, a new Examiner had been assigned and on December 30, 2003, he issued a non-final Office Action rejecting all claims as either anticipated (claims 12 and 20) by U.S. Patent 4,817,600 to Herms et al or published application 2003/0009215 to Mayer. Claims 12-27 were also rejected under 35 U.S.C. §103(a) citing Cornish 6,132,389 in view of the Mayer published application. Appellant's attorney responded with an amendment on January 13, 2004, narrowing the independent claims 12 and 20 and arguing for their allowability.

The Examiner thereupon caused a Final Action to be mailed on February 5, 2004, again rejecting all of the claims, repeating the same grounds as presented in his December 30, 2003 Office Action and presenting as "motivation" for the § 103(a) combination, a solution to a non-

existing problem with prior art intravascular guidewires containing nickel, i.e., adverse tissue reaction.

On March 3, 2004, appellant paid the fee for a continued prosecution application and filed a Request for Reconsideration, arguing a failure on the part of the Examiner to establish a *prima facie* case of obviousness based on the combination of U.S. Patent 6,132,389 to Cornish et al in view of published application 2003/0009215 to Mayer.

In response, the Examiner issued a further non-final Action on March 25, 2004, again rejecting all claims and presenting a rationale that attempted to refute the points made in the Request for Reconsideration of March 3, 2004.

On May 12, 2004, appellant filed an amendment to the specification and an argument supported by a § 132 Declaration from Dr. Jeffrey Chambers, a practicing cardiologist, and a person of more than ordinary skill in the art relating to intravascular guidewire design and manufacture. The Declaration rebuts the Examiner's contentions on why it would be obvious from the Cornish patent and the Mayer published application to make an intravascular guidewire whose core is Beta III titanium alloy.

On August 24, 2004, the Examiner issued another final rejection of claims 12-27 stating that the applicant's response of May 12, 2004 was sufficient to overcome the previous § 103(a) rejection based on the Cornish '389 patent and Cornish in view of Mayer, but that now asserted that the claimed invention would have been obvious from the teachings of the Cornish '389 patent in view of U.S. Patent 4,817,600 to Herms et al.

At this point, a personal interview was scheduled and held on October 27, 2004 with the Examiner and his supervisor, Mr. Eric Winak. During the interview, the inventor, Stephen Nuss, and Dr. Chambers demonstrated and compared the performance of two prior art guidewires, one made of Nitinol alloy and the other of stainless steel with one made with the titanium molybdenum alloy of the present invention. The Examiners were also shown a thrombus filter device of the Herms et al patent. At the conclusion of the interview, it was agreed that if the claims were amended to recite further structure applicable to intravascular guidewires, the claims would be patentable over the combination of Cornish in view of Herms. The amended claims, however, would be subject to a further search.

A second Request for Continued Examination was filed on November 1, 2004 along with an amendment responding to the August 24, 2004 Office Action. Claims 13-15 and 21-23

were canceled and independent claims 12 and 20 were amended in accordance with the understanding arrived at during the interview of October 27, 2004.

On December 3, 2004, the Examiner sent out a further, non-final Action no longer asserting invalidity under §103(d) based on the combination of Cornish with Herms, but now rejects all of the claims on a different combination. Independent claims 12 and 20 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent 5,984,679 to Farzin-Nia et al. All claims were also rejected under § 103(a) based on U.S. Patent 4,776,330 to Chapman et al in view of the Cornish '389 patent.

Appellant thereupon filed a responsive amendment on December 20, 2004. It amended independent claims 12 and 20 to specifically recite an "intravascular guidewire for insertion into the vascular system of a patient during the course of a catheterization procedure" to overcome the §102 rejection based on the Farzin-Nia '679 patent which related to a method of making a dental file. In arguing for allowability over the obviousness rejection, appellant's attorney charged that the Examiner had misread the Chapman reference dealing with a kit for stabilizing a broken femur bone.

On March 4, 2005, the USPTO mailed a Notice of Non-Compliant Amendment for failure to use proper "status identifiers". The previous amendment was then re-submitted, with the status indicators changed. This occurred on March 14, 2005.

Next, a Final Rejection was mailed on May 5, 2005, in which all claims were rejected solely on § 103(a) grounds, again relying on the Chapman '330 patent in view of the Cornish et al '389 patent.

Appellant responded on May 5, 2005, amending claim 12 to correct a typographical error and submitting a further Rule 132 Declaration by Dr. Chambers, pointing out that his reading of the Chapman reference, as a person skilled in the intravascular guidewire art, did not suggest making an intravascular guidewire from the titanium, molybdenum alloy being claimed by appellant.

The Examiner then mailed an Advisory Action on August 9, 2005, stating that the Declaration by Dr. Chambers was entered, but that claims 12, 16-20 and 24-27 remained rejected. A Notice of Appeal was filed on August 30, 2005.

What appellant believes to be a true copy of the claims presently under appeal appears in Claims Appendix attached to this Brief.

IV. STATUS OF AMENDMENTS

All amendments submitted in this application, which are referenced above, are believed to have been entered and are presently considered to be of record.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to an intravascular guidewire of the type used to introduce a catheter to a desired target area in the vascular system of a human body for diagnostic or treatment purposes. To introduce a working catheter to the desired target area, for example, a stenosed coronary blood vessel, an intravascular guidewire is introduced through a small puncture wound in the groin area leading to the femoral artery. The guidewire is advanced through the vascular system until its distal end is proximate the ostium of the target coronary vessel. A diagnostic catheter or a balloon catheter is then advanced along the guidewire until its distal end is adjacent the target.

In percutaneous translumenal coronary angioplasty, the distal end of the guidewire is advanced through the right or left femoral artery, the right or left iliac artery, the abdominal aorta, the thoracic aorta, the aortic arch and into the right atrium of the heart. From there the guidewire is made to pass through the coronary sinus to the target coronary vessel to be treated. A balloon catheter is then advanced over the guidewire under radiography or angiography and once the balloon expander on the catheter is inflated, it presses the stenotic lesion into the wall of the blood vessel, rendering the blood vessel more patent.

To advance the guidewire into the desired branch at a bifurcation in a coronary artery, the distal end of the guidewire must be formed into an appropriate shape by the interventional cardiologist. Also, it must possess adequate flexibility, pushability and torqueability so that the distal tip portion can be steered to the target location. More particularly, the distal end of the guidewire must be controllably rotated smoothly in a one-to-one relationship with rotation of its proximal end. Intermittent rotation with sudden snapping of the distal end makes it difficult to route through the vascular system.

Prior art guidewires have conventionally been made either from stainless steel or from a shape memory alloy such as nitinol. As is explained in applicant's specification, stainless steel guidewires tend to kink when bent. While stainless steel guidewires have adequate pushability,

they tend not be flexible enough to easily bend inside the vascular system. Nitinol guidewires, on the other hand, tend to be too springy and are subject to snapping, especially when negotiating a tortuous path in the vascular system. Also, Nitinol guidewires tend not to have good pushability and readily get hung up when rotated while extending around a curved path. Further, Nitinol guidewires possess a shape memory characteristic making it difficult for a physician to form a bend in the tip portion of the guidewire with his fingers.

Appellant has invented an intravascular guidewire for use in catheterization procedures in which titanium, molybdenum alloy, as specified in the independent claim 20 on appeal, is used as the core wire. As set out in independent claim 20, the invention relates to an intravascular guidewire 10 (pg. 8, ln. 8) adapted for insertion into the vascular system of a patient during the course of a catheterization procedure (pg. 6, ln. 9-11). It is formed using a titanium, molybdenum alloy wire (pg. 6, ln. 17). Specifically, the alloy includes between about 75% to 83% titanium, between about 8% to about 14% molybdenum, between about 4% to 8% zirconium and about 2% to 6% tin by weight (pg. 7, ln. 1-3). The wire 10 has a diameter in a range of from 0.005 in. and 0.040 in. over a predetermined length dimension (pg. 10, ln. 6-8) and has a proximal end portion 12 and a distal end portion 14 (pg. 8, ln. 8-9) where the distal end portion 14 is tapered to a lesser diameter than the diameter of the proximal end portion 12 (pg. 9, ln. 5). The distal end portion terminates in a rounded distal tip 16 (pg. 8, ln. 12).

Independent claim 12 differs from claim 20 only in that it is of a slightly narrower scope. It more precisely specifies the alloy of the wire as comprising 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight (pg. 6, ln. 21-22).

Guidewires made from this alloy are found to possess properties that fall between those made from stainless steel and from the nickel titanium (Nitinol). The titanium, molybdenum alloy guidewire invented by applicants possess a stiffness that is about 42% of that of stainless steel and it exhibits a better pushability than guidewires made of Nitinol. Moreover, applicant's titanium molybdenum alloy guidewire is easier to torque because it is less springy and will not tend to bind against the walls of a blood vessel in traversing a tortuous path and then suddenly spin in an uncontrolled manner as the torque on the proximal end is slowly increased.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The statutory provision of 35 U.S.C. § 103(a) forms the sole legal basis for the rejection of claims 12, 16-20 and 24-27. The references relied upon by the Examiner include U.S. Patent No. 4,776,330 to Chapman et al and U.S. Patent No. 6,132,389 to Cornish et al.

The only issue to be decided on appeal is whether the combination of these two references cited by the Examiner demonstrate that the subject matter of claims 12, 16-20 and 24-27 fails to meet the requirement for patentability imposed by 35 U.S.C. § 103.

VII. ARGUMENT

A. Grouping of Claims.

Appellant believes that all of the claims on appeal may stand or fall with claim 20 and, hence, the main thrust of the arguments will be directed to the invention defined by claim 20, which is deemed to be the broadest claim in the application.

Independent claim 20 is directed to an intravascular guidewire that is adapted for insertion into the vascular system of a patient during the course of a catheterization procedure that comprises a titanium molybdenum alloy wire where the constituents of the alloy include between about 75% and about 83% titanium, between about 8% and about 14% molybdenum, between about 4% and about 8% zirconium and between about 2% and about 6% tin by weight. The titanium molybdenum alloy wire has a diameter in a range of from 0.005 in. to 0.040 in. over a predetermined length dimension thereof. Claim 20 further specifies that the distal end portion of the wire be tapered to a lesser diameter than the diameter of the proximal end portion and that the distal end portion terminates in a rounded tip.

B. The Cited Art.

(1) Chapman et al. 4,776,330.

The Chapman et al. '330 patent is directed to a "kit" to be used by orthopedic surgeons in mending fractures in the femur. As set forth in the patent, the kit comprises (1) an elongated epiphyseal/metaphyseal implant having a leading end portion adapted to grip bone; (2) an intramedullary rod; (3) an angled side plate having an elongated plate portion adapted to be secured to the outer cortical wall of the femoral shaft and an integral hollow sleeve extending at an angle from one end of the plate portion allowing the hollow sleeve to extend into the femur when the plate portion is secured to the cortical wall; and (4) a device for connecting the

epiphyseal/emtaphyseal implant to the intramedullary rod adjacent to one end of the rod. Further, the kit may include an elongated bone plate that is connectable to the angled side plate along with a plurality of threaded, self-tapping, cortical bone screws and other related hardware.

The Chapman et al. '330 patent at column 4, line 16, states that the components of the kit are preferably formed from a titanium-based alloy, such as 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin. The advantage stated for this alloy is that it is physiologically inert and, therefore, reduces the potential for adverse tissue reactions when compared to stainless steel. Brief mention is made at column 12, line 56 of a guidewire 25, but no where in the Chapman et al. '330 patent is it indicated that the guidewire 25 is a part of the "kit" whose components are made from the specified titanium, molybdenum alloy. More importantly, and as indicated in the Declaration Under 37 C.F.R. §1.132 by Dr. Jeffrey Chambers dated April 20, 2004, contained in the Evidence Appendix hereto, the guidewire 25 in the Chapman et al. reference would only be 10-12 in. long and need not navigate any bends or curves. Hence, persons skilled in the art would not discern from the Chapman et al. reference that the guidewire mentioned therein would have the necessary properties to make it suitable for use as an intravascular guidewire for use in catheterization procedures.

In asserting that the Chapman et al. '330 patent teaches a guidewire made from titanium-molybdenum alloy of the type being claimed, even though it does not specifically say so, the Examiner refers to column 13, lines 56-63 of the Chapman et al. reference. Here, it indicates that after the expansion sleeve and plunger have been employed to lock the implant in place within the head and neck of the femur, that the guidewire 25 and the insertion rod 21 are removed from the patient's bone, but that, alternatively, the insertion rod 21 (Figure 3) and the guidewire 25 might be left in place in the patient's bone to form part of the implanted elongated bone implant. From this, the examiner concludes, erroneously we believe, that the guidewire must be made from the titanium-molybdenum alloy. This is a *non-sequitur*.

(2) Cornish et al. 6,132,389.

As stated in the Abstract of the '389 patent, the disclosure is directed to a guidewire having an elongate core member with a distally tapered portion and having a flexible body member disposed around this tapered distal section. While the guidewire of the '389 patent is especially designed for intravascular catheterization procedures, its specifically teaches that the

core member of the guidewire be either stainless steel or a nickel titanium alloy (Nitinol) or a combination thereof, but can also consist of any material that yields the approximate mechanical properties of stainless steel or Nitinol. See column 3, lines 41-46, of the '389 patent. There is no disclosure in the '389 patent for the use of the titanium molybdenum alloy as specified in appellant's claim 20.

C. Authorities and Arguments.

In determining the propriety of a rejection under 35 U.S.C. §103, it is well settled that the obviousness of an invention cannot be established by combining the teachings of the prior art, absence some teaching, suggestion or incentive supporting the combination. See *In Re Fine*, 837 F.2d 1071, 5 USPQ 2d 1596 (Fed. Cir. 1998). A test for obviousness is what the combined teachings of the references, taken as a whole, would have suggested to those having ordinary skill in the art. See *In Re Kaslow*, 707 F.2d 1366, 217 U.S.P.Q. 1089 (Fed. Cir. 1983). During patent examination, the U.S. Patent Office bears the initial burden of presenting a *prima facie* case of unpatentability. See *In Re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q. 2d 1443 (Fed. Cir. 1992). When the U.S. Patent Office fails to meet this burden, the appellant is entitled to the patent. However, when a *prima facie* is made, the burden shifts to the appellant to come forward with evidence and/or arguments supporting patentability. Patentability *vel non* is then determined on the entirety of the record, by a preponderance of the evidence and the weight of the argument. See *In Re Baisecki*, 745 F.2d 1468, 223 U.S.P.Q. 785 (Fed. Cir. 1984).

The burden of establishing a *prima facie* case of obviousness thus rests upon the Examiner and can only be satisfied by showing an objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led such individual to combine the relevant teachings of the cited references. It is error to reconstruct the appellant's claimed invention from the prior art by using the appellant's claim as a "blueprint". When prior art references require selective combination to render a subsequent invention unpatentable for obviousness, there must be some reason for the combination other than the hindsight obtained from the invention itself. See *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 227 U.S.P.Q. 543 (Fed. Cir. 1985). For the reasons discussed, the prior art references cited by the Examiner do not suggest the invention, as a whole, defined by claim 20 in the above-captioned application.

"To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the Examiner to show a motivation to combine the references that create the case of obviousness". *In Re Rouffet*, 149 F.3d 1350, 47 U.S.P.Q. 2d 1453 (Fed. Cir. 1998). "(T)he "suggestion to combine" requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness". *In Re Rouffet*, supra.

In analyzing whether claimed subject matter is properly rejected under 35 U.S.C. §103(a) based upon a combination of prior art references, two factors must be considered: (1) whether the prior art would have suggested to one or ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those or ordinary skill would have a reasonable expectation of success. *In Re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

In rejecting claim 20 based upon the combination of Chapman et al. '330 in view of Cornish et al. '389, the Examiner acknowledges that Cornish does not teach or suggest an intravascular guidewire having a titanium molybdenum alloy core wire. As mentioned, Cornish teaches stainless steel or Nitinol or any material that yields the approximate mechanical properties of stainless steel or Nitinol.

To overcome this deficiency, the Examiner attempts to combine the Cornish reference with the Chapman et al. reference. The Examiner offered as motivation that some persons have an allergic reaction to nickel and that this would lead a person skilled in the art away from using nickel as a constituent of a guidewire. However, as Dr. Chambers points out in his Declaration of April 20, 2004:

> "In the field of guidewires there is no issue with nickel sensitivity in the body. Many guidewires in popular use today have nickel in them without causing any allergic reactions. Indeed, guidewires containing nickel are in wide use and there is no literature that I am aware of indicating a sensitivity to nickel in association with their use. The reasons for this are that there is relatively limited dwell time of guidewires in the body, most are placed for less than one hour. Even with permanently implanted atrial septal defect (ASD) closure devices used to repair holes in the heart with a high nickel content of 55%, I am not aware of any reported cases of nickel sensitivity. Secondly, guidewires are usually coated with

lubricious materials such that the surface of the guidewire itself is not exposed to body tissue and therefore will not cause an allergic reaction."

As held in *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 60 U.S.P.Q. 3d 1001 (Fed. Cir. 2001), "The genius of invention is often a combination of known elements which, in hindsight, seems preordained. To prevent hindsight invalidation of patent claims, the law requires some 'teaching, suggestion or reason' to combine the cited references." No teaching, suggestion or reason to combine is offered by the references being cited. Further, there is nothing to indicate that anyone, not relying on hindsight, would, from the two references cited, arrive at the invention set forth in appellant's claim 20. Since nickel sensitivity is not a problem with prior art coronary guidewires, the fact that Beta Titanium III is non-allergenic is not a "motivation" for its use as the Examiner has contended.

It further appears that the Examiner has misread the Chapman et al. '330 patent. In his Official Action of May 5, 2005, the Examiner erroneously states that "Chapman et al. discloses a guidewire capable of insertion into a vascular system of a patient during the course of a catheterization procedure". As mentioned above, the guidewire 25 in the Chapman et al. '330 patent is for insertion into a rigid, rectilinear tube that is to be inserted into a cored out marrow space in a segment of a bone. As Dr. Chambers avers in his Rule 132 Declaration of July 1, 2005, that Chapman et al. describes the use of a "guidewire" in supporting/guiding a reamer used to core out a cylindrical bore in a bone and to insert an anchor in the bore, but such a guidewire would only be about one foot long and need not navigate any bends or curves. Dr. Chambers, a person of more than ordinary skill in the art relating to intravascular guidewires, further opines that even if it is assumed *arguendo* that the guidewire 25 in the Chapman et al. '330 patent were made of a titanium, molybdenum, zirconium, tin alloy, it would not in anyway suggest to a person skilled in the art that the alloy would lend itself to an intravascular guidewire that is typically 90 in. to 120 in. in length and that must have a requisite pushability, torqueability and malleability characteristic that would allow it to be advanced through the twists and turns of the vascular system in going from an area in the groin into a target blood vessel in the heart.

As is explained in appellant's patent specification, by fabricating a guidewire whose core wire comprises titanium, molybdenum, zirconium, tin alloy of the composition defined by

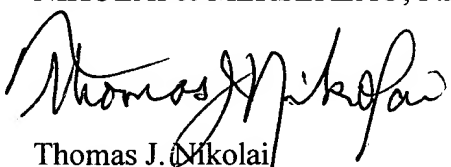
independent 20, a guidewire is achieved that has properties in between those possessed by stainless steel and Nitinol-based guidewires. In particular, the resulting guidewire possesses a tip portion that is malleable and can be shaped by the cardiologist at the time of the procedure. Further, its torqueability characteristics provide a one-to-one rotational displacement of the distal end of the guidewire as a torque is applied to its proximal end. The titanium molybdenum alloy has a moderate stiffness that is about 42% of that of stainless steel and is therefore more flexible than stainless steel for better bendability while negotiating through the tortuous path leading from an entry point in the femoral artery and progressing upward through the abdominal and thoracic aorta and into a right chamber of the heart. The titanium molybdenum alloy that appellant invented is found to be stronger and has improved pushability when compared with a Nitinol guidewire. It is submitted that appellant has made a valuable contribution to the art relating to the fabrication and use of intravascular guidewires for use in catheterization procedures and should be entitled to the grant of a patent thereon.

VIII. CONCLUSION

There is nothing in the cited references to suggest the combination set forth appellant's claim 20. Thus, it is submitted that the Board should find the invention as claimed to be "new, useful and non-obvious". The Examiner has not sustained the burden of establishing a *prima facie* case of obviousness, and, therefore, rejection based on 35 U.S.C. §103(a) should not stand. Appellant is convinced that the present claims are patentable and it is respectfully requested that the Final Rejection be reversed and the claims being appealed allowed.

Respectfully submitted,

NIKOLAI & MERSEREAU, P.A.



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CERTIFICATE OF MAILING

I hereby certify that the foregoing Second Revised Appeal Brief for the Appellant including Claims Appendix and Evidence Appendix (in triplicate), in application Serial No. 09/760,136, filed on January 12, 2001, of Stephen Nuss entitled "Titanium Molybdenum Alloy Guidewire" along with a Transmittal Letter are deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Mail Stop APPEAL BRIEF - PATENTS, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, postage prepaid, on November 15, 2006.

Date of Signature: November 15, 2006.

Linda J. Rice
On Behalf of Thomas J. Nikolai
Attorney for Appellant

VIII. CLAIMS APPENDIX

Listing of Claims Under Appeal:

12. An intravascular guidewire adapted for insertion into the vascular system of a patient during the course of a catheterization procedure, comprising: a titanium molybdenum alloy wire having approximately 78% titanium, 11.5% molybdenum, 6% zirconium and 4.5% tin by weight, the wire having a diameter in a range of from 0.005 inch and 0.040 inch over a predetermined length dimension thereof, said wire having a proximal end portion and a distal end portion that is tapered to a lesser diameter than the diameter of the proximal end portion and that terminates in a rounded distal tip.

16. The guidewire as in claim 12 having,

the distal end portion with a helical coil attached, and where the coil touches a distal tip of the guidewire, the coil providing springiness proximate the distal tip inhibiting kinking of the coil.

17. The guidewire as in claim 12 having,

a rounded distal tip member on the end of the distal end portion of the wire to prevent the distal end of the wire from penetrating tissue in the wall of a body lumen upon passage of the guidewire through the body lumen.

18. The guidewire as in claim 12 wherein,

the wire has a lubricious polymer coating.

19. The guidewire as in claim 12 wherein,

the wire has a hydrophilic coating.

20. An intravascular guidewire adapted for insertion into the vascular system of a patient during the course of a catheterization procedure comprising a titanium molybdenum alloy wire having approximately between about 75 % and about 83 %titanium, between about 8 % and about 14 %molybdenum, between about 4 % and about 8 % zirconium and between about 2 % and about 6 % tin by weight, the wire having a diameter in a range of from 0.005 inch and 0.040 inch over a predetermined length dimension thereof, said wire having a proximal end portion and a distal end portion where the distal end portion is tapered to a lesser diameter than the diameter of the proximal end portion and terminates in a rounded distal tip.

24. The guidewire as in claim 20 having coil attached to a distal tip member such that the coil provides springiness at the distal tip portion to prevent kinking of the coil.

25. The guidewire as in claim 20 having,

a distal tip member on the distal end portion to prevent the distal end of the wire from penetrating tissue in the wall of said body passageway.

26. The guidewire as in claim 20 wherein,

the wire has a lubricious polymer coating thereon.

27. The guidewire as in claim 20 wherein,

the guidewire has a hydrophilic coating thereon.

IX. EVIDENCE APPENDIX

1. Declaration Under 37 C.F.R. §132 of Dr. Jeffrey W. Chambers dated April 20, 2004. Entered by Examiner in Official Action of August 24, 2004.

2. Declaration Under 37 C.F.R. §132 of Dr. Jeffrey W. Chambers dated July 1, 2005. Entered by Examiner in Advisory Action of August 9, 2005.

3. Cornish et al. U.S. Patent 6,132,389. Entered by Official Action of December 30, 2003.

4. Chapman et al. U.S. Patent 4,776,330. Entered by Official Action of December 3, 2004.

X. RELATED PROCEEDINGS APPENDIX

As stated in Section II of Appellant's Appeal Brief, there are no other court decisions, appeals or interferences known to the owner of the subject application that would have any bearing on the Board's decision on the present appeal.